# APPENDIX G

# REPORT TO THE AQUATIC NUISANCE SPECIES TASK FORCE: GENERIC NON-INDIGENOUS AQUATIC ORGANISMS RISK ANALYSIS REVIEW PROCESS

# REPORT TO THE AQUATIC NUISANCE SPECIES TASK FORCE

# GENERIC NONINDIGENOUS AQUATIC ORGANISMS RISK ANALYSIS REVIEW PROCESS

**(For Estimating Risk Associated with the Introduction of Nonindigenous Aquatic Organisms and how to Manage for that Risk)**

**Risk Assessment and Management Committee**
**Aquatic Nuisance Species Task Force**
**Aquatic Nuisance Prevention and Control Act of 1990**

October 21, 1996

# Current and Former Members of the Risk Assessment and Risk Management Committee

Walter Blogoslawski
NOAA, National Marine Fisheries service
Former Member

Joseph McCraren
National Aquaculture Association
Former Member

Richard Guadiosi
U.S. coast Guard
Former Member

Fred **Kern**
NOAA National Marine Fisheries service
Current Member

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USDA, Animal and Plant Health Inspection service
Current Member, RAM Chairperson

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U.S. Army Corps of Engineers
Current Member

Mike Troyer
U.S. Environmental Protection Agency
Former Member

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USGS Biological Resource Division
Current Member

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National Aquaculture Association
Current Member

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Former Member

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Pet Industry Joint Advisory Council
Current Member

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U.S. Fish and Wildlife Service
Former Member

Jay Troxel
U.S. Fish and Wildlife Service
Current Member

Bill van der Schalie
U.S. Environmental Protection Agency
Current Member

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# I. INTRODUCTION

## Objective of the Review Process

The Risk Assessment and Management (RAM) Committee was initiated by, and is under the auspices of, the Aguatic Nuisance Species Task Force (Task Force). The Task Force was created for the purpose of developing a strategy in which the appropriate government agencies could meet the goals of the Aquatic Nuisance Prevention and Control Act of 1990. The Task Force was ".. established to coordinate governmental efforts related to nonindigenous aquatic species in the United States with those of the private sector and other North American interests" (ANSP, 1992). The Task Force is co-chaired by the U.S. Fish and Wildlife Service and the National Oceanic and Atmospheric Administration.

The Generic Nonindigenous Aquatic Organisms Risk Analysis Review Process (hereafter referred to as the Review Process) is the risk process developed through the RAM committee to help meet the requirements of the Aquatic Nuisance Prevention and Control Act.

The objective of the Review Process is to provide a standardized process for evaluating the risk of introducing nonindigenous organisms into a new environment and, if needed, determining the correct risk management steps needed to mitigate that risk.

The Review Process provides a framework where scientific, technical, and other relevant information can be organized into a format that is understandable and useful to managers and decision makers. The Review process was developed to function as an open process with early and continuous input from all identified interested parties.

The Review Process was designed to be flexible and dynamic enough to accommodate a variety of approaches to nonindigenous organism risk depending on the available resources, accessibility of the biological information, and the risk assessment methods available at the time of the assessment. The Review Process may be used as a purely subjective evaluation or be quantified to the extent possible or necessary depending on the needs of the analysis. Therefore, the process will accommodate a full range of methodologies from a simple and quick judgmental process to an analysis requiring extensive research and sophisticated technologies.

The specific function of the Review Process is to:

- **RISK ASSESSMENT -- Develop a process that can be used to:**

  **a) evaluate recently established nonindigenous organisms**

b) evaluate nonindigenous organisms proposed for deliberate introduction
c) evaluate the risk associated with individual pathways (i.e. ballast water, aguaculture, aquarium trade, fish stocking, etc.)

- **RISK MANAGEMENT** -- Develop a practical operational approach to maximize a balance between protection and the available resources for:

  a) reducing the probability of unintentional introductions
  b) reducing the risk associated with intentional introductions

## The History and Development of the Review Process

The Review Process was modified from the Generic Non-Indigenous Pest Risk Assessment Process (Orr, et al, 1993) developed by the USDA's Animal and Plant Health Inspection Service (APHIS) for evaluating the introduction of nonindigenous plant pests. The APHIS process has been thoroughly tested both within and outside of the agency with numerous completed individual organism assessments and three high risk pathway studies.

The development of the Review Process has been synchronous and functionally tied to the development of various ecological risk assessment methodologies and nonindigenous organism issues. Foremost was the National Research Council's workshops and meetings for the development of the "Ecological Paradigm" (NRC, 1993). The Review Process's basic approach and philosophy borrows heavily from the NRC's project.

Other major projects and reports which have influenced the direction of the Review Process are: The Environmental Protection Agency's "Ecological Framework" (EPA, 1992a) and associated documents (EPA, 1992b, 1992c, 1994); the United States Congress Office of Technology Assessment's nonindigenous species report OTA, 1993); and the Forest Service's pest risk assessments on nonindigenous timber pests (USDA, FS, 1991, 1992, 1993).

In addition to the above projects and numerous other pertinent work the following quality criteria (modified from Fischoff et al. 1981) were used in designing the Review Process:.

- **Comprehensive - The assessment should review the subject in detail and identify sources of uncertainty in data extrapolation and measurement errors. The assessment should evaluate the quality of its cwn conclusions. The assessment should be flexible to accommodate new information.**

- **Logically Sound - The risk assessment should be up-to-date and rational, reliable, justifiable, unbiased, and sensitive to different aspects of the problem.**

- **Practical - A risk assessment should be commensurate with the available resources.**

- **Conducive to Learning - The risk assessment should have a broad enough scope to have carry-over value for similar assessments. The risk assessment should serve as a model or template for future assessments.**

- **Open to Evaluation - The risk assessment should be recorded in sufficient detail and be transparent enough in its approach that it can 'be reviewed and challenged by qualified independent reviewers.**

## Risk Analysis Philosophy

The risk assessment process allows for analysis of factors for which the dimension, characteristics, and type of risk can be identified and estimated. By applying analytical methodologies, the process allows the assessors to utilize qualitative and quantitative data in a systematic and consistent fashion.

The ultimate goal of the process is to produce quality risk assessments on specific nonindigenous aquatic organisms or with nonindigenous organisms identified as being associated with specific pathways. The assessments should strive for theoretical accuracy while remaining comprehensible and manageable; and the scientific and other data should be collected, organized and recorded in a formal and systematic manner.

The assessment should be able to provide a reasonable estimation of the overall risk. All assessments should communicate effectively the relative amount of uncertainty involved and, if appropriate, provide recommendations for mitigation measures that reduce the risk.

Caution is required to ensure that the process clearly explains the uncertainties inherent in the process and to avoid design and implementation of a process that reflects a predetermined result. Quantitative risk assessments can provide valuable insight and understanding; however, such assessments can never capture all the variables. Quantitative and qualitative risk assessments should always be buffered with careful human judgment Goals that cannot be obtained from a risk assessment are:

1. A risk assessment cannot determine the acceptable risk level. What risk, or how much risk, is acceptable depends on how a person, or agency, perceives that risk. Risk levels are value judgments that are characterized by variables beyond the systematic evaluation of information.

2. It is not possible to determine precisely whether, when, or how a particular introduced organism will become established. It is equally impossible to determine what specific impact an introduced organism will have. The best that can be achieved is to estimate the likelihood that an organism may be

introduced and estimate its potential to do damage under favorable host/environmental conditions.

The ability of an introduced organism to become established involves a mixture of the characteristics of the organism and the environment in which it is being introduced. The level of complexity between the organism and the new environment is such that whether it fails or succeeds can be based on minute idiosyncrasies of the interaction between the organism and environment. These cannot be predicted in advance by general statements based only on the biology of the organism. In addition, even if extensive information exists on a nonindigenous organism, many scientists believe that the ecological dynamics are so turbulent and chaotic that future ecological events cannot be accurately predicted.

If all were certain, there would not be a need for risk assessment. Uncertainty, as it relates to the individual risk assessment, can be divided into three distinct types:

a) uncertainty of the process -- (methodology)
b) uncertainty of the assessor(s) -- (human error)
c) uncertainty about the organism -- (biological and environmental unknowns)

Each one of these presents its own set of problems. All three types of uncertainty will continue to exist regardless of future developments. The goal is to succeed in reducing the uncertainty in each of these groups as much as possible.

The "uncertainty of the process" requires that the risk methodologies involved with the Review Process never become static or routine but continue to be modified when procedural errors are detected and/or new risk methodologies are developed.

"Uncertainty of the assessor(s)" is best handled by having the most qualified and conscientious persons available conduct the assessments. The quality of the risk analysis will, to some extent, always reflect the quality of the individual assessor(s).

The "uncertainty about the organism is the most difficult to respond to. Indeed, it is the biological uncertainty more than anything else that initiated the need for developing a nonindigenous risk process. Common sense dictates that the caliber of a risk assessment is related to the quality of data available about the organism and the ecosystem that will be invaded. Those organisms for which copious amounts of high quality research have been conducted are the most easily assessed. Conversely, an organism for which very little is know-n cannot be easily assessed.

A high degree of biological uncertainty, in itself, does not demonstrate a significant degree of risk. However, those organisms which demonstrate a high degree of biological uncertainty do represent a real risk. The risk of importing a damaging nonindigenous organism (for which little information is known) is probably small for any single organism but the risk becomes much higher when one considers the vast number of these organisms that must be considered. It is not possible to identify which of the "unknowns" will create problems -- only assume that some will. Demonstrating that a pathway has a "heavy" concentration of nonindigenous organisms for which little information is present may, in some cases (based on the "type" of pathway and the "type" of organisms), warrant concern. However, great care should be taken by the assessor(s) to explain why a particular nonindigenous organism load poses a significant risk.

This need to balance "demonstrated risks" against “biological uncertainty" can lead assessors to concentrate more on the uncertainty than on known facts. To prohibit or restrict a pathway or specific nonindigenous organism, the reasons or logic should be clearly described.

Risk assessments should concentrate on demonstrated risk. Applying mitigating measures based on well documented individual nonindigenous pests will frequently result in a degree of mitigation against other organisms demonstrating high biological uncertainty that might be using the same pathway.

If we accept that "it is not possible to determine whether a particular introduced organism will become established", and "it is equally impossible to determine what specific impact an introduced organism will have", then we might be asked, "what value is there in doing risk assessments, which consist of assessing the probability of establishment and the consequence of establishment?*'. The risk assessment process is an effective tool for estimating potential in a systematic fashion.

Some of the information used in performing a risk assessment is scientifically defensible, some of it is anecdotal or based on experience, and all of it is subject to the filter of perception. However, we must provide an estimation based on the best information available and use that estimation in deciding whether to allow the proposed activity involving the nonindigenous organism and, if so, under what conditions.

The assessment should evaluate risk in order to determine management action. Estimations of risk are used in order to restrict or prohibit high risk pathways, with the goal of preventing the introduction of nonindigenous pests.

When conducting risk assessments for government agencies, the most serious obstacles to overcome are the forces of historical precedent and the limitations presented by legal parameters, operational procedures, and political pressure. In order to focus the assessment as much as possible on the biological factors of risk, all assessments need to be completed in an atmosphere as free of regulatory and political influences as possible,

The following quote is taken from the NRC's 1983 Red Book on "Risk Assessment in the Federal Government: Managing the Process":

> We recommend that regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies".

This can be translated to mean that risk assessments should not be policy-driven. However, the Red Book then proceeded with a caveat:

> "The importance of distinguishing between risk assessment and risk management does not imply that they should be isolated from each other; in practice they interact, and communication in both directions is desirable and should not be disrupted".

This can be translated to mean that the risk assessment, even though it must not be policy-driven, must be ***policy-relevant.*** These truths continue to be valid (NRC, 1993).

## II. THE REVIEW PROCESS FOR CONDUCTING PATHWAY ANALYSES AND ORGANISM RISK ASSESSMENTS

The need for a risk assessment starts either with the request for opening a new pathway which might harbor nonindigenous aquatic organisms or the identification of an existing pathway which may be of significant risk. All pathways showing a potential for nonindigenous organism introduction should receive some degree of risk screening. Those pathways that show a high potential for introducing nonindigenous organisms should trigger an in-depth risk assessment.

The following details of the Review Process focus on evaluating the risk of nonindigenous organisms associated with an identified pathway. Figure 1, on page 8, outlines the flow of a pathway analysis, dividing the process into initiation, risk assessment, and risk management. Specific organisms needing evaluation which are not tied to a pathway assessment would proceed directly to the Organism Risk Assessments" box in Figure 1 (page 8) and the "Organism Risk Assessments" section starting on page 10.

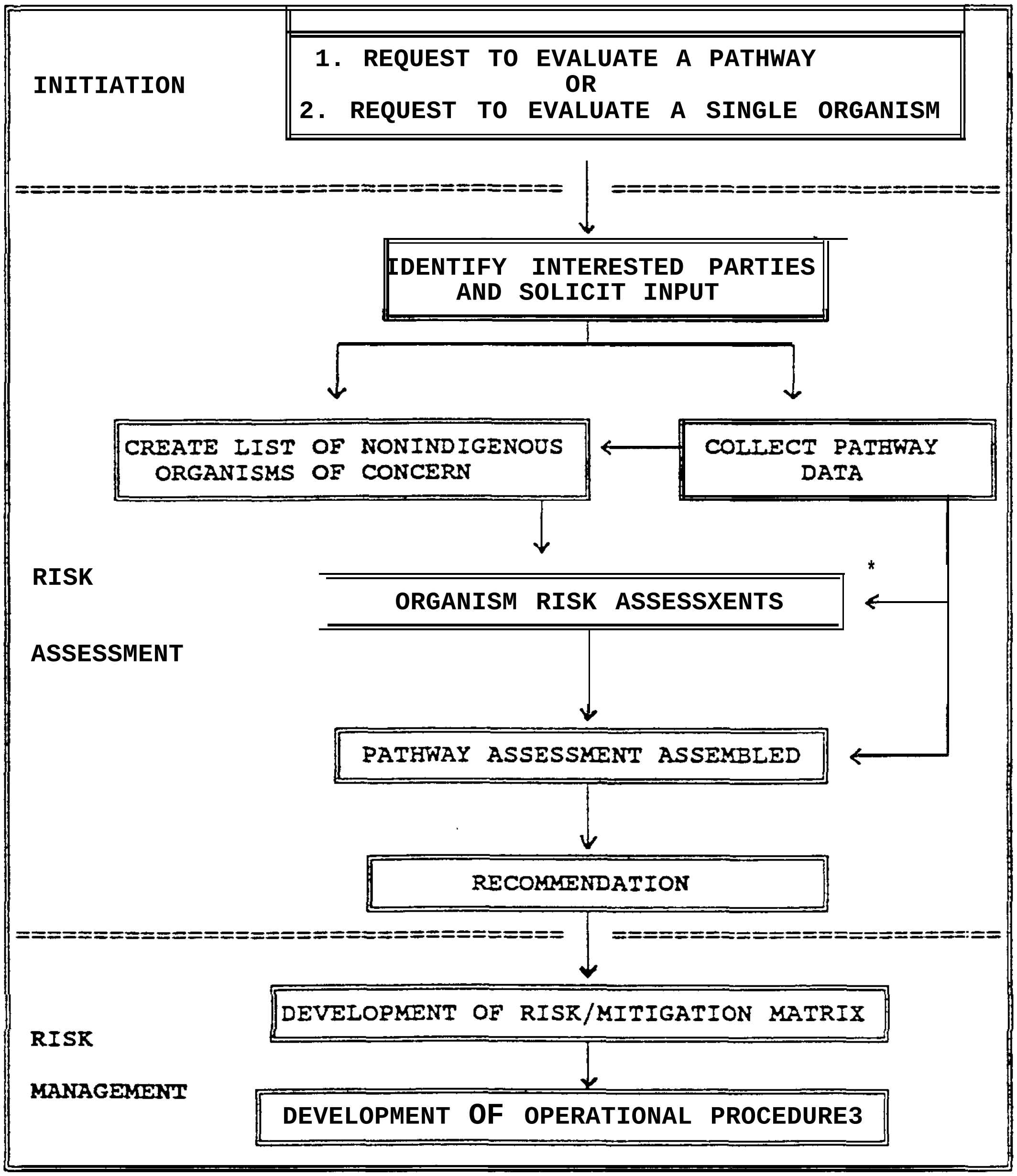
### Collecting Pathway Data

Specific information about the pathway must be collected. This information, coupled with additional data (if necessary), would fulfill the "Collect Pathway Data" element in Figure 1, page 8.

Specific information needed about the pathway will vary with the "type" of pathway (i.e. ballast water, aquaculture, aquarium trade, fish stocking, etc.). The following generalized list of information has been useful in other nonindigenous risk assessments.

**1) Determine exact origin(s) of organisms associated with the pathway.**
**2) Determine the numbers of organisms traveling within the pathway.**
**3) Determine intended use or disposition of pathway.**
**4) Determine mechanism and history of pathway.**
**5) Review history of past experiences and previous risk assessments (including foreign countries) on pathway or related pathways.**
**6) Review past and present mitigating actions related to the pathway.**

**FIGURE 1. Pathway Analysis: Flow Chart showing the Initiation, Risk Assessment and Risk Management for a pathway.**




* = For details on the Organism Risk Assessment see Figure 2 "Risk Assessment Model" page 11. Pathways that show a high potential. for introducing nonindigenous aquatic organisms should trigger detailed risk analyses.

## Creating a List of Nonindigenous Aquatic Organisms of Concern

The next element in figure 1 (page 8) is "Create List of Nonindigenous Organisms of Concern". The following generalized process is recommended .

**STEP:l) Determine what organisms are associated with the pathway.**

**2) Determine which of these organisms qualify for further evaluation using the table below.**

| Category | Organism Characteristics | Concern |
|---|---|---|
| la | species nonindigenous not present in country (United States) | yes |
| lb | species nonindigenous, in country and capable of further expansion | yes |
| lc | species nonindigenous, in country and reached probable limits of range, but genetically different enough to warrant concern and/or able to harbor another nonindigenous pest | yes |
| 1d | species nonindigenous, in country and reached probable limits of range and not exhibiting any of the other characteristics of lc | no |
| 2a | species indigenous, but genetically different enough to warrant concern and/or able to harbor another non-indigenous pest, and/or capable of further expansion | yes |
| 2b | species indigenous and not exhibiting any of the characteristics of 2a | no |

**3) Produce a list of the organisms of concern from (step** 2) **categories la, lb, lc, and 2a. Taxonomic confusion or uncertainty should also be noted on the list.**

**4) Conduct Organism Risk Assessments from the list of organisms developed in step 3.**

Based on the number of organisms identified and the available resources, it may be necessary to focus on fewer organisms than those identified using the above table. When this is necessary it is desirable that the organisms chosen for complete risk assessments be representative of all the organisms identified. A standard methodology is not available because the risk assessment process is often site or species specific. Therefore, professional judgement by scientists familiar with the aquatic organisms of concern is often the best tool to determine which organisms are necessary for effective screening.

This screening has been done using alternative approaches. Different approaches can be found in each of the three log commodity risk assessments (USDA, Forest Service, 1991, 1992, 1993).

## Organism Risk Assessments

The Organism Risk Assessment element in figure 1 (page 8) is the most important component of the Review Process used in evaluating and determining the risk associated with a pathway. The Organism Risk Assessment can be independent of a pathway assessment if a particular nonindigenous organism needs to be evaluated. Figure 2, on page 11, represents the Risk Model which drives the Organism Risk Assessment.

The Risk Assessment Model is divided into two major components the "probability of establishment" and the "consequence of establishment". This division reflects how one can evaluate an nonindigenous organism (e.g. more restrictive measures are used to lower the probability of a particular nonindigenous organism establishing when the consequences of its establishment are greater).

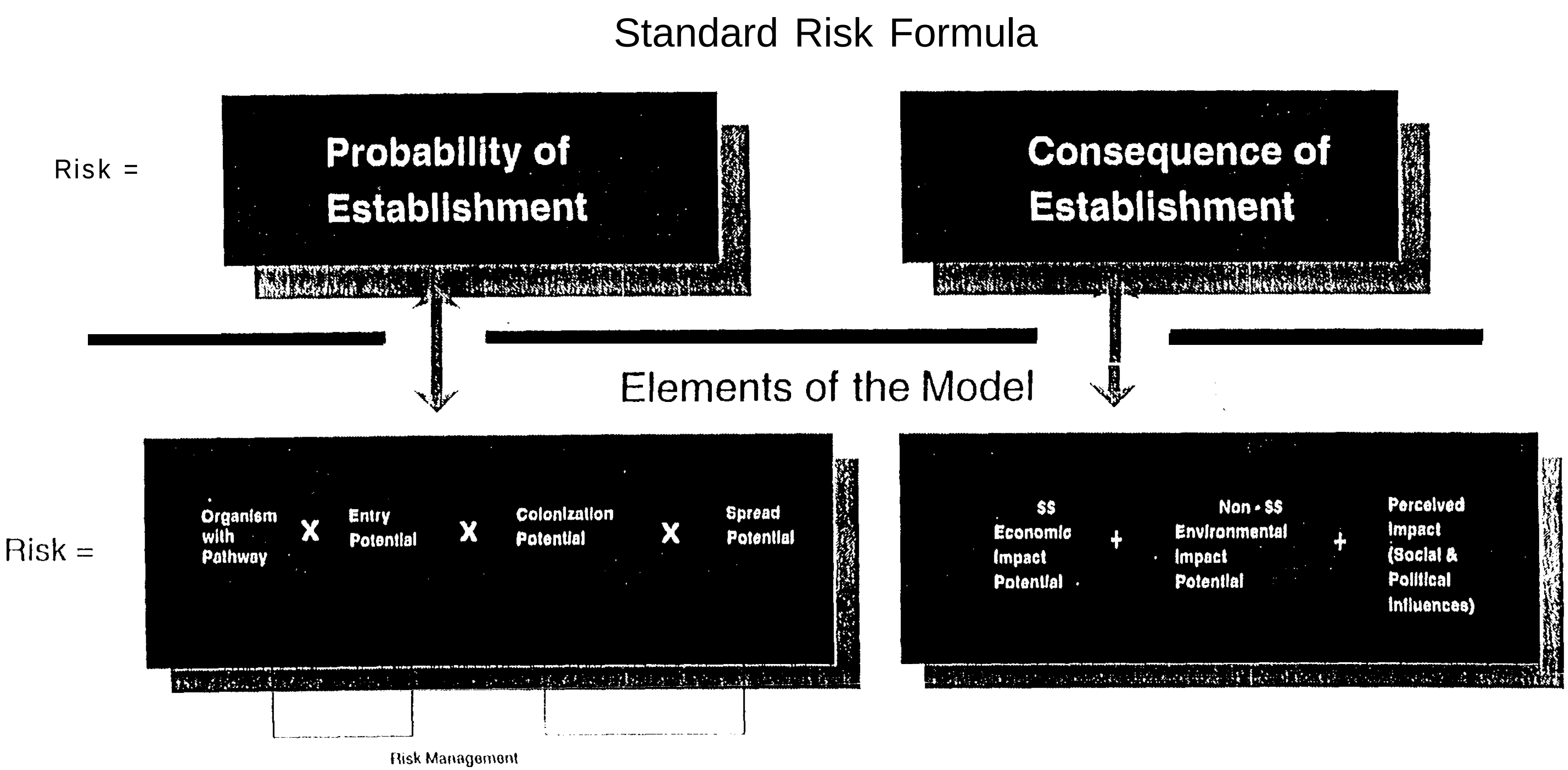
The Risk Assessment Model is a working model that represents **a** simplified version of the real world. In reality the specific elements of the Risk Model are not static or constant, but are truly dynamic showing distinct temporal and spatial relationships. Additionally, the elements are not equal in weighing the risk nor are they necessarily independent. The weight of the various elements will never be static because they are strongly dependent upon the nonindigenous organism and its environment at the time of introduction.

The two major components of the Risk Assessment Model are further divided into 7 basic elements which serve to focus scientific, technical, and other relevant information into the assessment. Each of these 7 basic elements are represented on the Risk Assessment Form (Appendix A, page 22) as probability or impact estimates. These may be determined using quantitative or subjective methods. See Appendix B (page 25) for a minimal subjective approach.

The strength of the assessment is that the information gathered by the assessor(s) can be organized under the seven elements. The cumulative information under each element provides the data to assess the risk for that element. Whether the methodology used in making the risk judgement for that element is quantitative, qualitative, or a combination of both; the information associated with the element (along with its references) will function **as the** information source. Placing the information in order of descending risk under each element will further communicate to

FIGURE 2

# Risk Assessment Model




- For model simplification the various elements are depicted as being independent of one another
- The order of the elements in the model does not necessarily reflect the order of calculation

reviewers the thought process of the assessor(s).

Adequate documentation of the information sources makes the Review Process transparent to reviewers and helps to identify information gaps. This transparency facilitates discussion if scientific or technical disagreement on an element-rating occurs. For example, if a reviewer disagrees with the rating that the assessor assigns an element the reviewer can point to the information used in determining that specific element-rating and show what information is missing, misleading, or in need of further explanation. Focusing on information to resolve disagreements will often reduce the danger of emotion or a preconceived outcome from diluting the quality of the element-rating by either the assessors or the reviewers.

The characteristics and explanations of the seven elements of the Risk Assessment Model are as follows:

### A. Elements -- Group 1: Assess Probability of Organism Establishment

When evaluating an organism not associated with a pathway, or an organism recently introduced, the first 2 elements under Group 1 would automatically be rated as high because entry into the new environment is either assumed or has already occurred.

1. Nonindigenous Aquatic Organisms Associated with Pathway (At Origin) -- Estimate probability of the organism being on, with, or in the pathway.

The major characteristic of this element is: Does the organism show a convincing temporal and spatial association with the pathway.

2. Entry Potential -- Estimate probability of the organism surviving in transit.

Some of the characteristics of this element include:: the organism's hitchhiking ability in commerce, ability to survive during transit, stage of life cycle during transit, number of individuals expected to be associated with the pathway; or whether it is deliberately introduced (e.g. biocontrol agent or fish stocking).

3. Colonization Potential -- Estimate probability of the organism colonizing and maintaining a population.

Some of the characteristics of this element include: the organism coming in contact with an adequate food resource, encountering appreciable abiotic and biotic environmental resistance, and the ability to reproduce in the new environment.

4. Spread Potential -- Estimate probability of the organism spreading beyond the colonized area.

Some of the characteristics of this element include: ability for natural dispersal, ability to use human activity for dispersal, ability to readily develop races or strains, and the estimated range of probable spread.

**B. Elements -- Group II: Assess Consequence of Establishment**

5. Economic Impact Potential -- Estimate economic impact if established.

Some of the characteristics of this element include: economic importance of hosts, damage to crop or natural resources, effects to subsidiary industries, exports, and control costs.

6. Environmental Impact Potential -- Estimate environmental impact if established.

Some of the characteristics of this element include: ecosystem destabilization, reduction in biodiversity, reduction or elimination of keystone species, reduction or elimination of endangered/threatened species, and effects of control measures. If appropriate, impacts on the human environment (e.g. human parasites or pathogens) would also be captured under this element.

7. Perceived Impact (Social & Political Influences) -- Estimate impact from social and/or political influences.

Some of the characteristics of this element include: aesthetic damage, consumer concerns, and political repercussions.

Often the assessor feels uncomfortable dealing with the categories of Economic and Perceived Impact. However, information found by an assessor relating to these categories maybe helpful in making risk management decisions. The assessor should not be expected to reflect, or second guess, what an economist or politician would conclude but rather to present information gathered on the organism that would (or could) have an affect in these areas.

The elements considered under Consequences can also be used to record positive impacts that a nonindigenous organism might have for example its importance as a biocontrol agent, aquatic pet, sport fish, scientific research organism, or based on its use in aquaculture. The elements in the case of deliberate introductions would record information that will be useful in determining the element-rating that would be a balance between the cost, the benefit, and the risk of introducing the nonindigenous organism.

The Risk Assessment Form (Appendix A, page 22) should be flexible. Each nonindigenous organism is unique. The assessor needs to have the freedom to modify the form to best represent the risk associated with that particular organism. The seven elements need to be retained to calculate the risk but other sections may be added or subtracted. If the assessor feels that information, ideas, or recommendations would be useful, they should be included in the assessment. The assessor can combine "like" organisms into a single assessment if their biology is similar (e.g. tropical aquarium fish destined to temperate North America).

The number of risk assessments to be completed from the list of nonindigenous organisms in a particular pathway depends on several factors. These include the amount of individual organism information, available resources, and the assessor's judgement concerning whether the completed assessments effectively represent the pathways' nonindigenous organism risk.

The source of the statements and the degree of uncertainty the assessor associated with each element needs to be recorded in the Risk Assessment. The use of the Reference Codes at the end of each statement, coupled with the use of the Uncertainty Codes for each element, fulfill these requirements. Both the Reference Codes and the Uncertainty Codes are described in Appendix A on page 24.

If a federal agency uses the Review Process for potential environmental problems, much of the information may contribute to meeting that agency's National Environmental Policy Act(NEPA)reguirements. When both NEPA documentation and a risk assessment are warranted, the two should be coordinated so that resources are not duplicated. Although a risk assessment is similar to an Environmental Impact Statement (EIS) the risk assessment differs by focusing on the probability of occurrence and the impact of that occurrence, while an EIS generally places its emphasis on who or what will be impacted. Therefore, a risk assessment is more likely to clarify possible outcomes, determine or estimate their probabilities of occurrence, and succeed in recording the degree of uncertainty involved in making the predictions.

### Summarizing Organism and Pathway Risk

An estimate of risk is made at three levels in the Review Process. The first, places a risk estimate on each of the seven elements within the Risk Assessment (element-rating). The second, combines the seven risk element estimates into a Organism Risk Potential (ORP) which represents the overall risk of the organism being assessed. The third, links the various ORPs into a Pathway Risk Potential (PRP) which will represent the combined risk associated with the pathway.

The assigning of either a quantitative or a qualitative estimate to an individual element, and determining how the specific elements in the Model are related, and how the estimates should be combined are the most difficult steps in a risk assessment. There is not a "correct" formula for completing these steps. Various methodologies such as geographical information systems, climate and ecological models, decision-making software, expert systems, and graphical displays of uncertainty may potentially increase the precision of one or more elements in the Risk Assessment Model. Indeed, risk assessments should never become so static and routine that new methodologies can not be tested and incorporated.

When evaluating new technologies and approaches it is important to keep in mind that the elements of the Risk Assessment Model are dynamic, chaotic, and not equal in value. New technologies or approaches which may be appropriate for assessing one organism may be immaterial or even misleading in evaluating another organism.

The high, medium, and low approach presented in Appendix B page 25 for calculating and combining the various elements is judgmental. The process in Appendix B is a generic minimum for determining and combining the element estimates and not necessarily "the best way it can be done".

The strength of the Review Process is that the biological statements under each of the elements provide the raw material for testing various approaches. Therefore, the risk assessments will not need to be re-done to test new methods for calculating or summarizing the ORP and PRP.

On risk issues of high visibility, examination of the draft assessment should be completed by pertinent reviewers not associated with the outcome of the assessment. This is particularly appropriate when the risk assessments are produced by the same agency, professional society, or organization that is responsible for the management of that risk.

## ELEMENTS OF RISK MANAGEMENT AND OPERATIONAL REQUIREMENTS

The previous sections dealt with assessing the level of risk associated with a particular pathway or organism. Once the risk assessment is completed, it is the responsibility of risk managers to determine appropriate policy and operational measures.

A. Elements To Consider In Risk Management Policy:

- **Risk assessments (including uncertainty and quality of data)**
- **Available mitigation safeguards (i.e., permits, industry standards, prohibition,inspection)**
- **Resource limitations (i.e., money, time, locating qualified experts, needed information)**
- **Public perceptions/perceived damage**
- **Social and political consequences**
- **Benefits and costs should be addressed in the analysis**

B. The following four risk management operational steps should be accomplished:

- **Step 1: Maintain communication and input from interested parties;**
- **Step 2: Maintain open communication between risk managers and risk assessors;**
- **Step 3: Match the available mitigation options with the identified risks;**
- **Step 4: Develop an achievable operational approach that balances resource protection and utilization.**

STEP 1: Participation of interested parties should be actively solicited as early as possible. All interested parties should be carefully identified because adding additional interested parties late in the assessment or management process can result in revisiting issues already examined and thought to have been brought to closure. All identified interested parties should be periodically brought up-to-date on relevant issues.

STEP 2: Continuous open communication between the risk managers and the risk assessors is important throughout the writing of the risk assessment. This is necessary to ensure that the assessment will be policy relevant when completed. Risk Managers should be able to provide detailed questions about the issues that they will need to address to the risk assessors <u>before</u> the risk assessment is started. This will allow the assessors to focus the scientific information relevant to the questions (issues) that the risk managers will need to address.

As important as open communication is between risk managers and risk accessors, it is equally important that risk managers do not attempt to drive, or influence, the outcome of the assessment. Risk assessments need to be <u>policy-relevant</u> not <u>policy-driven</u>.

STEP 3: Matching the available mitigation options with the identified risks can sometimes be done by creating a mitigation matrix placing the organisms, or groups of organisms, identified in a specific pathway along one axis and the available mitigation options along the other. Where a specific organism, or group of organisms, meets a specific mitigation process in the matrix, the efficacy for control is recorded. Using this process it becomes apparent which mitigation or mitigations are needed to reduce the risk to an acceptable level. The mitigation matrix (page 18) was used in the mitigation report on New Zealand log imports (USDA, APHIS, 1992) which addresses the nonindigenous organisms identified in the New Zealand log risk assessment (USDA, FS, 1992).

STEP 4: Developing a realistic operational approach is not easy. Each new operational decision must consider a number of management, agency, and biological factors that will always be unique to any specific organism or pathway. However,, at an operational risk management level each step in the operational pyramid (page 19) is a process that needs to be examined before approval of the importation, or release, or action against, a nonindigenous organism or pathway is taken. These include the risk assessment, the development of conditions for entry to meet current industry or regulatory standards, effective mitigation of any identified potential nonindigenous aquatic organisms, feasibility of achieving the mitigation requirements, and finally, a system of monitoring to ensure that all mitigation requirements are maintained.

**MITIGATION MATRIX**

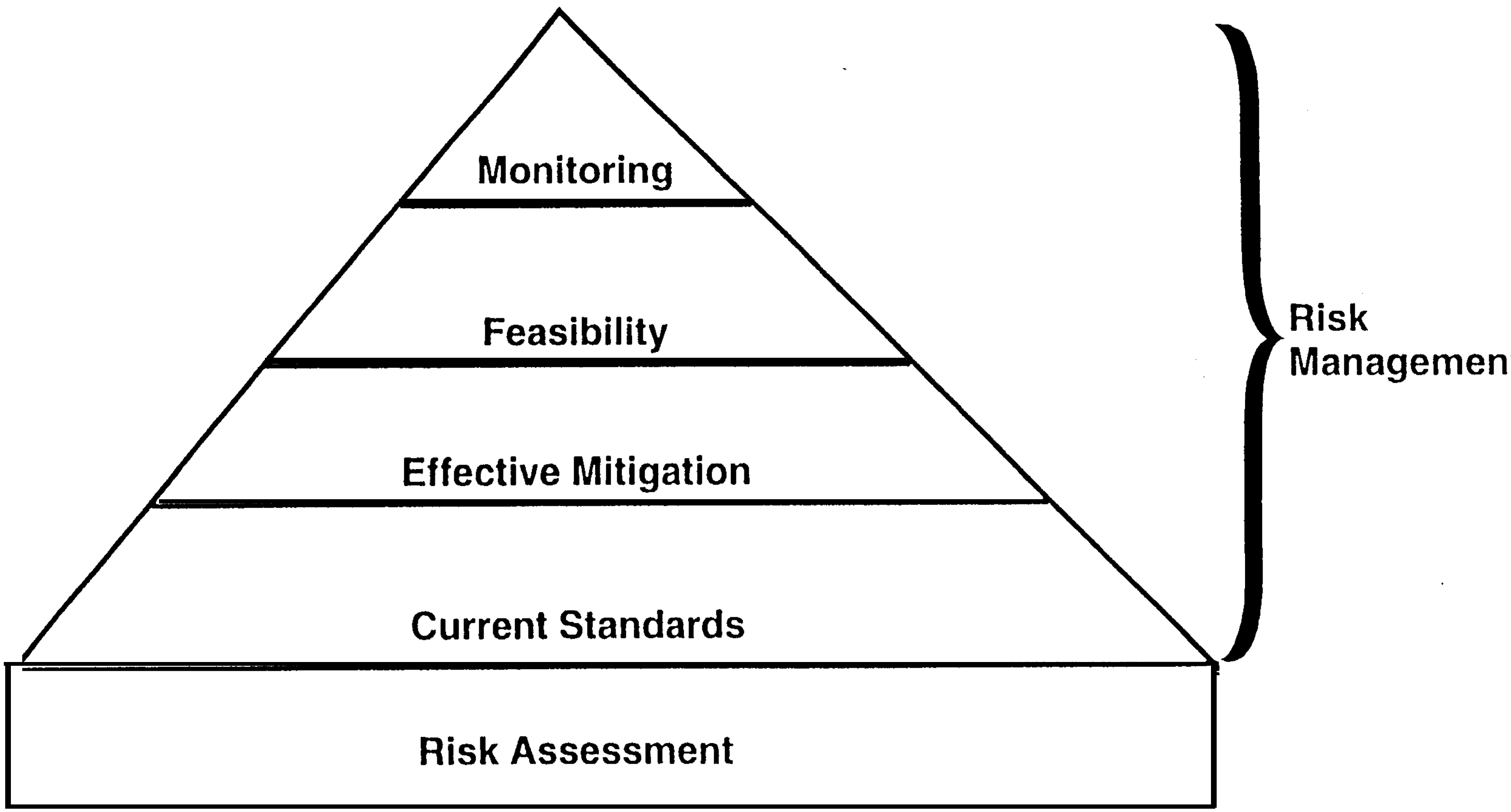
*Pinus radiata* logs from New Zealand
(Pathogens & Plant Feeding Insects vs. Mitigation)

| Mitigation Procedures in NEW ZEALAND | | | | | In USA | |
|---|---|---|---|---|---|---|
| ORGANISM | 30 DAY LIMIT | SAWLOG QUALITY ONLY | DE-BARKING | MB FUMI-GATION | AGENCY ENTRY REQ. | HEAT PROCESS SAWMILL |
| Bark Beetles | S | S | E | T | S | T |
| Platypus spp- | S | S | S | T | S | T |
| Sirex/ Fungus | S | E | S | E | S | T |
| Lepto-graphium | S | E | S | E | S | T |
| Kaloterm es | S- | E | S | T | S | T |
| Huhu beetles | S | E | S | E | S | T |
| Hitch hikers | S | S | E | T | S | T |
| Unknown Pests | S | S | S | E | S | T |

Key :

(S)ome reduction of pest risk expected (less than 95%)
(E)xtensive reduction (95 percent or more) of pest risk expected
(T)otal (100 percent or nearly 100 percent) reduction of pest risk expected

# Operational Pyramid (Risk Management)



## components of the Final Analysis

A completed Risk Analysis may contain the following:

- Tracking/Information Form or Section

This documents the analysis process and records information about why the assessment was done, who the assessment was done for, and information which might not be found in the assessment itself but could be useful background information for future reviewers. It also would contain information that would be helpful in determining (at a later date) the depth of the review, which resources were used and which methodologies were tried but not used in the final assessment. The main function of this form or section would be to provide additional transparency to the analysis and to provide a historical record for future reviewers.

- Pathway information form or section
- A complete list of the organisms of concern
- The individual Organism Risk Assessments
- Response to specific questions requested by risk managers
- Summation of the methodology used in determining the ORPs and PRPs
- Mitigation/risk matrix
- Detailed discussion associated with each level of the operational pyramid
- Summation and responses to outside reviewers

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## APPENDIX A:

**ORGANISM RISK ASSESSMENT FORM**
(With Uncertainty and Reference Codes)

**ORGANISM** ______________________ **FILE NO.** ________
**ANALYST** ______________________ **DATE** ________
**PATHWAY** ______________________ **ORIGIN** ________

I. LITERATURE REVIEW AND BACKGROUND INFORMATION
(Summary of life cylce, distribution, and natural history):

**II. PATHWAY INFORMATION (include references):**

**III. RATING ELEMENTS:** Rate statements as low, medium, or high. Place specific biological information in descending order of risk with reference(s) under each element that relates to your estimation of probability or impact. Use the reference codes at the end of the biological statement where appropriate and the Uncertainty Codes after each element rating.

**PROBABILITY OF ESTABLISHMENT**

| Element Rating (L,M,H) | Uncertainty Code (VC -VU) | |
|---|---|---|
| ______ | ______ | Estimate probability of the nonindigenous organism being on, with, or in the pathway. (Supporting Data with reference codes) |
| ______ , | ______ | Estimate probability of the organism surviving in transit. (Supporting Data with reference codes) |
| ______ , | ______ | Estimate probability of the organism successfully colonizing and maintaining a population where introduced. (Supporting Data with reference codes) |
| ______ , | ______ | Estimate probability of the organism to spread beyond the colonized area. (Supporting Data with reference codes) |

## CONSEQUENCE OF ESTABLISHMENT

| Element Rating (L,M,H) | Uncertainty Code (VC - VU) | |
|---|---|---|
| ______ , | ______ | Estimate economic impact if established. (Supporting Data with reference codes) |
| ______ , | ______ | Estimate environmental impact if established. (Supporting Data with reference codes) |
| ______ , | ______ | Estimate impact from social and/or political influences. (Supporting Data with reference codes) |

## IV. ORGANISM/PATHWAY RISK POTENTIAL: (ORP/PRP) __________

Probability of Establishment | Consequence of Establishment = ORP/PRP RISK

## V. SPECIFIC MANAGEMENT QUESTIONS:

## VI. RECOMMENDATIONS:

## VII. MAJOR REFERENCES:

## REFERENCE CODES TO ANSWERED QUESTIONS

| Reference Code | Reference Type |
|---|---|
| (G) | General Knowledge, no specific source |
| (J) | Judgmental Evaluation |
| (E) | Extrapolation; information specific to pest not available; however information available on similar organisms applied |
| (Author, Year) | Literature Cited |

## UNCERTAINTY CODES TO INDIVIDUAL ELEMENTS

| Uncertainty Code | Symbol | Description |
|---|---|---|
| Very Certain | vc | As certain as I am going to get |
| Reasonably Certain | RC | Reasonably certain |
| Moderately Certain | MC | More certain than not |
| Reasonably Uncertain | RU | Reasonably uncertain |
| Very Uncertain | W | A guess |

## APPENDIX B: JUDGMENTAL CALCULATION OF ORGANISM RISK AND PATHWAY RISK

### Step 1. Calculating the elements in the Risk Assessment

The blank spaces located next to the individual elements of the risk assessment form (Appendix A) can be rated using high, medium, or low. The detailed biological statements under each element will drive the judgmental process. Choosing a high, medium, or low rating, while subjective, forces the assessor to use the biological statements as the basis for his/her decision. Thus, the process remains transparent for peer review.

The high, medium, and low ratings of the individual elements cannot be defined or measured -- they have to remain judgmental. This is because the value of the elements contained under "probability of establishment" are not independent of the rating of the "consequences of establishment". <u>It is important to understand that the strength of the Review Process is not in the element-rating but in the detailed biological and other relevant information statements that motivates them</u>.

## Step 2. Calculating the Organism Risk Potential

The Organism Risk Potential and the Pathway Risk Potential ratings of high, medium, and low should be defined (unlike the element rating in step 1 which have to remain undefined). An example is provided of these definitions at the end of Appendix B page 29.

The following 3 steps must be completed in order to calculate the Organism Risk Potential.

### Step 2a. Determine Probability of Establishment

$$\text{Probability of Establishment} = \left[\begin{array}{l}\text{Organism}\\ \text{with}\\ \text{Pathway}\end{array}\right] \left[\begin{array}{l}\text{Entry}\\ \text{Potential}\end{array}\right] \left[\begin{array}{l}\text{Colonization}\\ \text{Potential}\end{array}\right] \left[\begin{array}{l}\text{Spread}\\ \text{Potential}\end{array}\right]$$

* * * * * * * * * *

The probability of establishment is assigned the value of the element with the lowest risk rating (example: a high, low, medium, and medium estimate for the above elements would result in a low rating).

Because each of the elements must occur for the organism to become established, a conservative estimate of probability of establishment is justified. In reality (assuming the individual elements are independent of each other) when combining a series of probabilities (such as medium - medium - medium) the probability will become much lower than the individual element ratings. However, the degree of biological uncertainty within the various elements is so high that a conservative approach is justified.

## Step 2b. Determine Consequence of Establishment

Consequence of Establishment = $\boxed{\text{Economic}}$ $\boxed{\text{Environmental}}$ $\boxed{\text{Perceived}}$

Consequence of Establishment =

| | | | |
|---|---|---|---|
| H | L,M,H | L,M,H | = H |
| L,M,H | H | L,M,H | = H |
| M | M | L,M,H | = M |
| M | L | L,M,H | = M |
| L | M | L,M,H | = M |
| L | L | M,H | = M |
| L | L | L | = L |

Note that the three elements that make up the Consequence of Establishment are not treated as equal. The Consequence of Establishment receives the highest rating given either the Economic or Environmental element. The Perceived element does not provide input except when Economic and Environmental ratings are low (see next to the last column on the above table).

**Step 2c. Determine Organism Risk Potential (ORP)**

**ORP RISK =** [PROBABILITY OF ESTABLISHMENT] [CONSEQUENCE OF ESTABLISHMENT]

**ORP RISK =**

| | | |
|---|---|---|
| High | High | = High |
| Medium | High | = High |
| Low | High | = Medium |
| High | Medium | = High |
| Medium | Medium | = Medium |
| Low | Medium | = Medium |
| High | Low | = Medium |
| Medium | Low | = Medium |
| Low | Low | = Low |

Here the conservative approach is to err on the side of protection. When a borderline case is encountered (lines 2, 4, 6, 8 on the above chart) the higher rating is accepted. This approach is necessary to help counteract the high degree of uncertainty usually associated with biological situations.

**Step 3. Determine the Pathway Risk Potential (PRP)**

| **ORP** | | **PRP** |
|---|---|---|
| Rating | Number | Rating |
| High | 1 or more | High |
| Medium | 5 or more | High |
| Medium | >0 but <5 | Medium |
| Low | All | Low |

The PRP reflects the highest ranking ORP. The only exception is when the number of medium risk organisms reaches a level at which the total risk of the pathway becomes high. The number, 5 or more, used in the above table is arbitrary.

**Definition of Ratings used for Organism Risk Potential and Pathway Risk Potential:**

Low = acceptable risk - organism(s) of little concern (does not justify mitigation)

Medium = unacceptable risk - organism(s) of moderate concern (mitigation is justified)

High = unacceptable risk - organism(s) of major concern (mitigation is justified)

When assessing an individual organism, a determination that the ORP is medium or high often becomes irrelevant because both ratings justify mitigation. When evaluating a pathway, the potential "gray area" between a PRP of medium and high may not be a concern for the same reason.

## APPENDIX C: DEFINITIONS (Aquatic Nuisance Species Act definitions in bold type)

**AQUATIC NUISANCE SPECIES - A nonindigenous species that threatens the diversity or abundance of native species or the ecological stability of infested waters, or commercial, agricultural, aquacultural or recreational activities dependent on such waters. Aquatic nuisance species include nonindigenous species that may occur in inland, estuarine and marine waters and that presently or potentially threaten ecological processes and natural resources. In addition to adversely affecting activities dependent on waters of the United States, aquatic nuisance species adversely affect individuals, including health effects.**

**AQUATIC SPECIES -** All animals and plants as well as pathogens or parasites of aquatic animals and plants totally dependent on aquatic ecosystems for at least a portion of their life cycle. Bacteria, viruses, parasites and other pathogens of humans are excluded.

**BALLAST WATER - Any water and associated sediments used to manipulate the trim and stability of a vessel.**

**CONTROL -** Activities to eliminate or reduce the effects of aquatic nuisance species, including efforts to eradicate infestations, reduce populations of aquatic nuisance species, develop means to adapt human activities and facilities to accommodate infestations, and prevent the spread of aquatic nuisance species from infested areas. Control may involve activities to protect native species likely to be adversely affected by aquatic nuisance species. Preventing the spread of aquatic nuisance species is addressed in the Prevention Element of the proposed Program; all other control activities are included in the Control Element.

**ECONOMIC IMPACT POTENTIAL -** The expected net change in society's net welfare which is the sum of the producers' and consumers' surpluses arising from changes in yield and cost of production caused by the pest.

**ECOSYSTEMS -** In the broadest sense, these are natural or "wild" environments as well as human environments, including infrastructure elements. An ecosystem may be an animal or plant in the case where the species involved is a pathogen or parasite.

**ENTRY POTENTIAL -** The relative ability of an organism to penetrate the borders of a given area within a time interval.

**ENVIRONMENTALLY SOUND - Methods, efforts, actions or programs to prevent introductions or control infestations of aquatic nuisance species that minimize adverse impacts to the structure**

**and function of an ecosystem and adverse effects on non-target organisms and ecosystems and emphasize integrated pest management techniques and nonchemical measures.**

**ESTABLISHED -** When used in reference to a species, this term means occurring as a reproducing, self-sustaining population in an open ecosystem, i.e., in waters where the organisms are able to migrate or be transported to other waters.

**EXCLUSIVE ECONOMIC ZONE** - The Exclusive Economic Zone of the United States established by Proclamation Number 5030 of March 10, 1983, and the equivalent zone of Canada.

**INDIGENOUS** - The condition of a species being within its natural range or natural zone of potential dispersal; excludes species descended from domesticated ancestors (OTA, 1993).

**INTENTIONAL INTRODUCTIONS -** The knowing import or introduction of nonindigenous species into, or transport through, an area or ecosystem where it was not previously established. Even when there is no intent to introduce an aquatic organism into an ecosystem, escapement, accidental release, improper disposal (e-g., "aquarium dumps") or similar releases are the virtual inevitable consequence of an intentional introduction, not an unintentional introduction.

Synonyms: Purposeful, Deliberate.

**INTEGRATED PEST MANAGEMENT** - The control of pests utilizing a practical, economical, and scientifically based combination of chemical, biological, mechanical or physical, and cultural control methods. Coordinated application of non-chemical control methods is emphasized in order to reduce or eliminate the need for pesticides. Integrated pest management is a balanced approach which considers hazard to the environment, efficacy, costs, and vulnerability of the pest. It requires: (1) identification of acceptable thresholds of damage; (2) environmental monitoring; and (3) a carefully designed control program to limit damage from the pest to a predetermined acceptable level.

**NATIVE** - Indigenous.

**NONINDIGENOUS SPECIES** - **Any species or other viable biological material that enters** an **ecosystem beyond its historic range, including any such organism transferred from one country into another** [Nonindigenous species include both exotics and transplants].

Synonyms: Introduced, Exotic, Alien, Foreign, Non-native, Immigrant, Transplants.

**ORGANISM** - Any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, viroids, viruses, or any entity characterized as living, related to the foregoing.

**PATHWAY** - The means by which aquatic species are transported between ecosystems.

**PREVENTION** - Measures to minimize the risk of unintentional introductions of nonindigenous aquatic species that are, or could become, aquatic nuisance species into waters of the United States.

**PUBLIC FACILITIES** - Federal, State, regional and local government-owned or controlled buildings, structures and other man-made facilities, including water intakes, boat docks, electrical power plants, locks and dams, levees, water control structures, and publicly-owned fish culture facilities. Electric generating stations, water supply systems and similar facilities operated by public utilities or other non-governmental entities are also considered public facilities.

**RISK** - Is the likelihood and magnitude of an adverse event.

**RISK ANALYSIS** - The process that includes both risk assessment and risk management.-

**RISK ASSESSMENT -** The estimation of risk.

**RISK COMMUNICATION** - The act or process of exchanging information concerning risk.

**RISK MANAGEMENT -** The pragmatic decision-making process concerned with what to do about the risk.

**SPECIES** - A group of organisms, all of which have a high degree of physical and genetic similarity, can generally interbreed only among themselves, and show persistent differences from members of allied species. Species may include subspecies, populations, stocks, or other taxonomic classifications less than full species.

**TRANSPLANTS-** Species native to North America which have been introduced into ecosystems where they did not occur prior to European colonization. In other words, such species did not historically occur in the location in question.

**UNINTENTIONAL INTRODUCTION - An introduction of nonindigenous species that occurs as a result of activities other than the purposeful or intentional introduction of the species involved, such as the transport of nonindigenous species in ballast or in water used to transport fish, mollusks or crustaceans for aquaculture or other purpose. Involved is the release, often**

**unknowingly, of nonindigenous organisms without any specific purpose. The virtually inevitable escapement, accidental release, improper disposal (e.g., "aquarium dumping") or similar releases of intentionally introduced nonindigenous species do not constitute unintentional introductions.**

Synonyms: Accidental, Incidental, Inadvertent.

**UNITED STATES** - The 50 States, the District of Columbia, Puerto Rico, Guam, and all other possessions and territories of the United States of America.

**VECTOR** - A biological pathway for a disease or parasite, i.e., an organism that transmits pathogens to various hosts. Not a synonym for Pathways as that term is used in the proposed Aquatic Nuisance Species Program.

**WATERS OF TEE UNITED STATES - The navigable waters and the territorial sea of the United States. Since aquatic: nuisance species can move or be transported by currents into navigable waters, all internal waters of the United States, including its territories and possessions, are included. The Territorial Sea of the United States is that established by Presidential Proclamation Number 5928 of December 27, 1988.**

Synonyms: United States Waters

# APPENDIX H
# OBSERVER COMMENTS AND LIST OF OBSERVERS

# APPENDIX H.  OBSERVERS' COMMENTS AND LIST OF OBSERVERS

The workshop agenda included an opportunity for observers to make public statements during the afternoon plenary sessions on January 7 and January 8.  At the discretion of each breakout group chair, observers were also provided an opportunity to participate in discussions during breakout group sessions.  A list of observers is provided at the end of this section.

Also included here are written comments received from Tony Amoriggi.  Mr. Amoriggi's comments, submitted in July 1997 in connection with the stakeholder meetings on the report of the JSA Shrimp Virus Work Group, were inadvertently omitted from the minutes of the stakeholder meetings.  Although Mr. Amoriggi was not present at the risk assessment workshop, his comments have been included here for reference.

**James Heerin**
**Shrimp Culture, II, Inc.**
**Roswell, Georgia**

Mr. Heerin commented about the composition of the peer review workshop panel.  He expressed the concern that no one from the shrimp processing industry was represented on the panel or on the shrimp processing workgroup, and he commented that there were only two people on the panel with any significant involvement in aquaculture production.

**Andrew Duda**
**A. Duda and Sons, Inc.**
**Oviedo, FL**

Mr. Duda cautioned that the media will focus on the executive summary of the workshop report.  He asked that the panel consider the media's likely reaction to the report, and its executive summary when applying the modified Aquatic Nuisance Species Task Force risk assessment methodology.  He also stated that it is necessary to separate issues, and look at them pragmatically.  Growers know that disease is a problem, and they want to be part of, and learn from the risk assessment process.  He also suggested that the likelihood of virus colonization is low; if the likelihood were high, the virus would have wiped out the South Carolina shrimp fishery shortly after it was observed there in aquaculture farms.

**David Whitaker**
**South Carolina Department of Natural Resources**
**Charleston, SC**

Mr. Whitaker stated that workshop participants need to consider that the risk of an event leading to the long-term, total annihilation of a fishery is an entirely different matter than the risk of an event in which the disease spreads, runs its course, and the population recovers.

**Mark Frischer**
**Skidaway Institute of Oceanography**
**Savannah, GA**

Mr. Frischer commented that shrimp viruses are a global issue, and shrimp represent a global industry. He noted that it is unwise not to consider the practices in the shrimp industry worldwide.

**Rolland Laramore**
**Bonney, Laramore, and Hopkins; Harbor Branch Oceanographic Institution**
**Vero Beach, FL**

Mr. Laramore questioned the ability of diagnostic procedures, specifically the gene probe, and PCR, to detect differences in viral strains (i.e., to distinguish between native, and non-native species).

He added that aquaculture species can migrate across international borders, and he added that there is no "fence" between the waters of Mexico, and the United States.

Mr. Laramore stated that work he performed with Ralston-Purina determined that viruses, and bacteria are killed by high temperatures during feed processing. He noted, however, that farmed shrimp, particularly those in hatcheries, and maturation systems, are fed both "natural", and processed feeds. "Natural" feeds include frozen shrimp, squid, and krill, which could carry the viruses with them. Shrimp Culture, Inc., avoided this problem by irradiating "natural" feed.

Mr. Laramore also stated that, within 2 or 3 years, the discussion is likely to focus on different strains of these viruses, some of which may prove to be local or native rather than nonindigenous.

He added that, to date, industry, and academia have not worked well together. He noted that many of the larger shrimp farms have qualified scientists on staff, but, so far, collaboration between industry, and academia has not occurred.

Mr. Laramore commented that he is disturbed that research that has come out of Honduras has been relegated to "nondata" status. The Honduran data come from samples of approximately 300 million to 400 million shrimp. He urged those who have not read his paper, "*Shrimp Culture in Honduras Following the Taura Syndrome Virus*," to do so, and stated that he would like to hear from people about any errors in the paper's assumptions.[1] He also stated that he believes that similar data from Panama and Ecuador may exist.

**Craig Browdy**
**South Carolina Department of Natural Resources, Waddell Mariculture Center**
**Bluffton, SC**

Dr. Browdy commented about the relevance of laboratory information in determining events that might occur in the wild. He urged the workshop participants to emphasize cell culture in its list of research needs. He suggested that cell culture methods for insects, and fish can determine the amount of virus in a sample, but he noted that these methods do not yet exist for crustacea. He also urged that time during the workshop be devoted to looking at the individual pathways of infection of aquaculture ponds in terms of the relative risks of infecting aquaculture stocks. Dr. Browdy concluded that this information will be very important for the risk management workshop.

**Jerome Erbacher**
**National Marine Fisheries Service (NMFS), Office of Industry, and Trade**
**Silver Spring, MD**

Mr. Erbacher stated that he worked for 3 years as the assistant to the NMFS aquaculture coordinator. He also explained that he was one of the authors of the report of the JSA Shrimp Virus Work Group.

Mr. Erbacher stated that aquaculture is "the canary in the coal mine." While aquaculture may be a partial cause of the introduction of nonindigenous viruses, he indicated that it is also the biggest victim of viral introductions, which have caused significant economic, and employment problems in the industry. Mr. Erbacher noted that the risk of introducing viruses from the wild to aquaculture operations is an important part of risk management for viral introductions, and that the upcoming NMFS management workshop will look extensively at this issue. He stated that any insight that the participants in the peer review workshop can provide about how these viruses are transferred from the wild to aquaculture will greatly assist the next phase of the risk management process.

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[1] Laramore, C.R. 1997. Shrimp culture in Honduras following the Taura syndrome virus. IV Central American Symposium on Aquaculture, Tegucigalpa, Honduras.

**Deyaun Boudreaux**
**Texas Shrimp Association**
**Port Isabel, TX**

Ms. Boudreaux stated that it is important to identify the natural host of each nonindigenous virus, if possible. On behalf of the wild shrimp fishery, she thanked the workshop participants for helping to find ways in which we can be better stewards of the ocean, and the habitat of penaeid shrimp.

July 27, 1997

Ms. Kate Schalk
Vice President
Eastern Research Group
110 Hartwell St.
Lexington,, MA 02173

Dear Ms. Schalk,

At the recent Virus Stakeholders meeting in Charleston, South Carolina, on July 15, 1997, an introductory statement was made by Dr. Kay Austin, stating that the only known study of which it was demonstrated that farm raised shrimp were responsible for the decline of the blue shrimp, *P. Stylirostris* occurred in the Gulf of California. This study was alleged to be reported in a thesis prepared by Carlos R. Pantoja Morales while studying the incidence of IHHNV in populations of shrimp off the coast of Sonora, Mexico.

Since I am fluent in Spanish, I asked for a copy of the study that Dr. Austin quoted, unfortunately no copies were available at the time of the meeting. After requesting a copy of said thesis, Dr. Tom Siewicki with the National Marine Fisheries Service, was kind enough to forward a copy to me for my review.

After having read said thesis, by Carlos Roberto Pantoja Morales, I find no data that relates to the incidence of pond raised shrimp and IHHNV in the wild population of *P. stylirostris*. In fact, there were no analyses of IHHNV reported in any farm raised shrimp in his thesis. The only shrimp samples analyzed and reported in this thesis were wild caught shrimp taken from 39 stations along the coast of Sonora, Mexico, and it should be noted, that the species collected were *P. vannamei*, *P. stylirostris* and *P. californiensis*.

Regards,

Tony Amoriggi

United States
Environmental
Protection Agency

# Shrimp Virus
# Peer Review and Workshop

Crystal Gateway Marriott
Arlington, VA
January 7-8, 1998

## Observers


**Kay Austin**
National Center
for Environmental Assessment
Office of Research
and Development
U.S. Environmental
Protection Agency
401 M Street, SW (8623)
Washington, DC 20460
202-260-5789
Fax:202-260-8719
E-mail:austin.kay@epamail.epa.gov

**Deyaun Boudreaux**
Environmental Director
Texas Shrimp Association
Postal Drawer AF
Port Isabel, TX 78578
956-943-3932
Fax:956-943-1743

**Craig Browdy**
Associate Marine Scientist
Shrimp Culture Specialist
Waddell Mariculture Center
South Carolina Department
of Natural Resources
P.O. Box 809
Bluffton, SC 29910
803-837-3795
Fax: 803-837-3487
E-mail:browdycl@musc.edu

**Steve Clapp**
Contributing Editor
Food Regulation Weekly
1101 Pennsylvania Avenue, SE
Washington, DC 20003
202-546-5086
Fax: 202-546-5983

**Andrew Duda**
Executive Vice President
A. Duda & Sons, Inc.
1975 West State Road 426
Oviedo, FL 32765
407-365-2143
Fax: 407-365-2147

**Jerome Erbacher**
Office of Industry and Trade
National Marine Fisheries Services
U.S. Department of Commerce
1315 East-West Highway
Room 3675
Silver Spring, MD 20910
301-713-2379 144
Fax: 301-713-2384
E-mail:jerome.erbacher@noaa.gov

**Mark Frischer**
Assistant Professor
Skidaway Institute
of Oceanography
10 Ocean Science Circle
Savannah, GA 31411
912-598-2308
Fax: 912-598-2310
E-mail:frischer@skio.peachnet.edu

**James Heerin**
Chairman
Shrimp Culture, Inc.
300 Grimes Bridge Road
Roswell, GA 30075
770-238-5195
Fax: 770-552-6577
E-mail:jheerin@agris.com

Frederick Kern
Marine Biologist
National Marine Fisheries Service
904 South Morris Street
Oxford, MD 21654
410-226-5193
Fax: 410-226-5925
E-mail:frederick.kern@noaa.gov

**Rolland Laramore**
President
Bonney, Laramore & Hopkins
443 22nd Place , SE
Vero Beach, FL 42962
561-563-0744

**Mike Mendelsohn**
Microbiologist
Office of Pesticides Program
U.S. Environmental Protection
Agency
401 M Street, SW (7511 W)
Washington, DC 20460
703-308-8715
Fax: 703-308-7026
Email:mendelsohn.mike@epamail.epa.gov

**Richard Orr**
Senior Entomologist
Animal & Plant Health
Inspection Service
U.S. Department of Agriculture
4700 River Road - Unit 117
Riverdale, MD 20732
301-734-8939
Fax: 301-734-5899

**Edwin Rhodes**
Aquaculture Coordinator
National Marine Fisheries Service
U.S. Department of Commerce
1315 East-West Highway
Room 14601
Silver Spring, MD 20910
301-713-2334
E-mail:edwin.rhodes@noaa.gov

**Angela Ruple**
Microbiologist
National Seafood
Inspection Laboratory
National Marine Fisheries Service
P.O. Drawer 1207
Pascagoula, MS 39568
601-762-7402
Fax: 601-769-9200
E-mail:aruple@triton.pas.nmfs.gov

**Cheryl Shew**
Ziegler Brothers, Inc.
P.O. Box 95
400 Gardner Station Road
Gardner, PA 17324
717-677-6181
Fax: 717-677-6826

**Bill van der Schalie**
National Center
for Environmental Assessment
Office of Research
and Development
U.S. Environmental
Protection Agency
401 M. Street, SW (8623)
Washington, DC 20460
202-260-4191
Fax: 202-260-6370
E-mail:vanderschalie.william@epamail.epa.gov

**David Whitaker**
Assistant Director of Fisheries
Management
South Carolina Department
of Natural Resources
P.O. Box 12559
Charleston, SC 29422
803-762-5052
Fax: 803-762-5412
E-mail:whitakerd@mrd.dnr.state.sc.us